

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve PET scanner services.

(2) PET is a covered clinical service for purposes of Part 222 of the Code. A PET scanner previously approved pursuant to Section 10 of these standards and recognized by the Department as a dedicated research PET scanner listed in the Department Inventory of PET Scanners, and now seeking approval to operate pursuant to sections 3, 4, or 5, shall be considered as a person requesting CON approval to initiate or expand, as applicable, a PET scanner service.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 17, 18, 19, 20, and 21, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use sections 14 and 15, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) The Department shall use Section 13, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Accelerator" means an apparatus, such as a linear accelerator or cyclotron, for accelerating charged particles to high energies by means of electromagnetic fields.

(b) "Acquisition of an existing PET scanner" means obtaining possession or control of an existing PET scanner from an existing PET scanner service by contract, ownership, lease, or other comparable arrangement.

(c) "Acquisition of an existing PET scanner service" means obtaining possession or control of an existing PET service and its unit(s) by contract, ownership, lease, or other comparable arrangement.

(d) "Anatomical site" means the physical area that can be imaged by a single PET scan.

(e) "Arterial sampling" means the insertion of an in-dwelling intra-arterial catheter for the withdrawal of arterial blood as part of a PET procedure.

(f) "Bed position" means the anatomical site being imaged. A change in bed position occurs when a different anatomical site is imaged and the scan requires the physical relocation of the patient relative to the PET scanner.

(g) "Central service coordinator" means the legal entity that has, or will have, operational responsibility for a mobile PET scanner service.

(h) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(i) "Cyclotron" means an apparatus for accelerating charged particles to high energies by means of electromagnetic fields.

(j) "Dedicated pediatric PET scanner" means a PET scanner approved pursuant to Section 11 of these standards, recognized by the Department as a dedicated pediatric PET scanner listed in the Department Inventory of PET Scanners, and is a PET scanner upon which at least 70% of the PET procedures are performed on patients under 18 years of age.

(k) "Dedicated research PET scanner" means a PET scanner approved pursuant to Section 10 of these standards and recognized by the Department as a dedicated research PET scanner listed in the Department Inventory of PET Scanners. The Department shall modify the Department Inventory of PET Scanners as applicable.

(l) "Department" means the state agency known as the Michigan Department of Community Health (MDCH).

(m) "Department inventory of PET scanners" or "Department Inventory" means the list, maintained by the Department on a continuous basis, of: (i) the PET scanners operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) PET scanners that are not yet operational but have a valid CON issued under Part 222; (iii) proposed PET scanners under appeal from a final Department decision or pending a hearing from a proposed decision issued under Part 222 of the Code; and (iv) proposed PET scanners that are part of a completed application under Part 222 of the Code.

(n) "Dynamic PET scan" means a PET scan that is closely timed to the administration of a radiopharmaceutical in order to capture the perfusion of the tracer.

(o) "Existing PET scanner" means a CON-approved and operational PET scanner used to provide PET services on the date an application is submitted to the Department.

(p) "Existing PET scanner service" means a CON-approved and operational scanner(s) used to provide PET services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.

(q) "Expand a fixed PET scanner service" means increasing the number of fixed PET scanners at the same geographic location of an existing fixed PET scanner service.

(r) "Expand a mobile PET scanner service" means the addition of a mobile PET scanner that will be operated by a central service coordinator in the same planning area in which the CSC is approved primarily to operate one or more mobile PET scanners as of the date an application is submitted to the Department.

(s) "FDG" means 2-{fluorine-18} fluoro-2-deoxy-D-glucose radiopharmaceuticals.

(t) "Health service area" or "HSA" means the groups of counties listed in Section 22.

(u) "Hospital" means a health facility licensed under Part 215 of the Code.

(v) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.

(w) "Initiate a mobile PET host site" means the provision of PET services at a host site that has not received any approved mobile PET services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease for the mobile PET service(s).

(x) "Initiate a PET scanner service" means begin operation of a PET scanner service, either fixed or mobile, at a geographic location that does not offer (or has not offered within the last consecutive 12-month period) approved PET scanner services and is not listed on the Department Inventory of PET Scanners on the date on which an application is submitted to the Department.

(y) "Institutional review board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(z) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and 1396i to 1396u.

(aa) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(bb) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(cc) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(dd) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.

(ee) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON. The mobile PET unit shall operate under a contractual agreement for the provision of PET services on a regularly scheduled basis at each host site, with a minimum of one visit per year.

(ff) "Out-state Michigan" means health service areas two (2) through eight (8).

(gg) "Patient visit" means a single session lasting no more than one day utilizing a PET scanner during which 1 or more PET procedures are performed.

(hh) "Pediatric patient" means any patient less than 18 years of age.

(ii) "PET data unit" means the result of the methodology as used in Section 17.

(jj) "PET equivalent" means the number calculated in accordance with Section 16 for a single patient visit.

(kk) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.

(ll) "PET scan" means one (1) or more PET procedures performed during a single patient visit.

(mm) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/CT scanner hybrids. If the PET/CT scanner will be used for computed tomography (CT) scans only in conjunction with the PET scan, then no separate CON is required for that CT use. The term does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence imaging, or similar technology.

(nn) "PET scanner services" or "PET services" means either the CON-approved utilization of a PET unit(s) at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

(oo) "Planning area" means the health service area(s), as applicable, and identified in Section 23.

(pp) "Radionuclide generator" means the source of radioactive material, other than an accelerator or nuclear reactor, used to produce radiopharmaceuticals.

(qq) "Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic purposes.

(rr) "Relocate a fixed PET scanner" means a change in the location of a fixed PET scanner(s) from the existing site to a different site within the relocation zone.

(ss) "Relocate an existing fixed PET scanner service" means a change in the location of a fixed pet scanner service and its unit(s) from the existing site to a different site within the relocation zone.

(tt) "Relocation zone" means a proposed site that is within a 10-mile radius of the existing fixed PET scanner service for a metropolitan statistical area county and a 25-mile radius of the existing fixed PET scanner service for a rural or micropolitan statistical area county, based upon documentation acceptable and verified by the Department.

(uu) "Replace a PET scanner" means an equipment change, other than an upgrade, involving a PET scanner that results in that applicant operating the same number of PET scanners before and after project completion.

(vv) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(ww) "SPECT" means single photon emission computed tomography.

- (xx) "Static PET scan" means any PET scan that is not dynamic.
- (yy) "Tracer" means a radiopharmaceutical developed for use in PET scanner services which allows the quantification and/or qualitative images of chemistry, metabolism, and/or perfusion in vivo.
- (zz) "Transmission scan" means transmission computed tomography using a sealed radioactive photon source or x-ray tube photon source applied to the attenuation correction of the emission scan data.
- (aaa) "Upgrade an existing PET scanner" means any equipment change that:
 - (i) does not involve a change in, or replacement of, the scanner;
 - (ii) does not result in an increase in the number of PET scanners;
 - (iii) does not result in a change in the type of PET scanner (e.g., changing a mobile PET scanner to a fixed PET scanner) or a change in manufacturer; and
 - (iv) involves a capital expenditure of less than \$500,000 in any consecutive 24-month period.
- (2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for all fixed services and mobile host sites

Sec. 3. (1) An applicant proposing to provide PET scanner services shall provide the following services and medical specialties:

- (a) nuclear medicine services, as documented on the certificate issued by the Department of Environmental Quality,
- (b) single photon emission computed tomography (SPECT) services,
- (c) computed tomography (CT) scanning services,
- (d) magnetic resonance imaging (MRI) services,
- (e) cardiac catheterization services
- (f) open heart surgery,
- (g) thoracic surgery,
- (h) cardiology,
- (i) oncology,
- (j) radiation oncology,
- (k) neurology,
- (l) neurosurgery, and
- (m) psychiatry.

If the applicant does not provide any of the services listed in this subsection at the same site at which the proposed PET scanner service will be located, the applicant shall include in the application written contracts or agreements with a hospital(s) located within the same planning area for the services not provided at the proposed PET scanner service site.

(2) If a proposed PET scanner service does not involve an on-site source of radiopharmaceuticals, an applicant must provide in the application a written contract or agreement that demonstrates that a reliable supply of radiopharmaceuticals will be available to the proposed PET scanner service.

Section 4. Requirements for approval for applicants proposing to initiate a PET scanner service

Sec. 4. (1) An applicant proposing to initiate a fixed PET scanner service shall project an operating level of at least 2,600 PET data units for each proposed PET scanner based on the methodology used in Section 17.

(2) An applicant proposing to initiate a mobile PET scanner service shall project 2,100 PET data units for each proposed mobile PET scanner based on the methodology used in Section 17.

(a) Of the 2,100 PET data units, the applicant(s) shall project a minimum of 360 PET data units, within the same planning area and a 20-mile radius of the proposed host site, for each proposed PET

scanner service site located in a planning area that does not include any rural or micropolitan statistical area counties and a minimum of 240 PET data units, within the same planning area as the proposed host site, for each PET scanner service site located in a planning area that includes any rural or micropolitan statistical area counties.

(b) The requirements of subsection (2) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant, the central service coordinator, demonstrates that the mobile PET scanner service operates predominantly outside of Michigan and that all of the following requirements are met:

(i) The proposed host site will be located in HSA 8.

(ii) The proposed host site in HSA 8 demonstrates a minimum of 240 PET data units based on the methodology in Section 17.

(3) Initiation of a mobile PET host site does not include the provision of mobile PET services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides, as applicable, each of the following:

(a) The host site has received mobile PET services from an existing approved mobile PET unit within the most recent 12-month period as of the date the application is submitted to the Department.

(b) The addition of a host site to a mobile PET scanner service will not increase the number of PET units operated by the central service coordinator or by any other person.

(c) The application is submitted to the Department prior to the provision of PET services on that network.

(d) A signed certification whereby the host site has agreed and assured that it will provide PET services in accordance with the terms for approval set forth in Section 14 and 15. The applicant also shall provide a current route schedule for the mobile PET scanner service.

(e) The central service coordinator requires, as a condition of any contract with each host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

(f) An applicant, whether a central service coordinator or a proposed host site, proposing to initiate a mobile PET host site to an existing mobile PET network or a mobile PET network that has been applied for under Section 5(3), shall not be required to demonstrate a minimum number of PET data units.

(4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing to initiate a fixed PET scanner service.

(b) The applicant is currently a host site being served by one or more mobile PET scanners.

(c) The applicant has received, in aggregate, the following:

(i) At least 4,500 PET equivalents, for an applicant in a metropolitan statistical area county, during the most recent 12-month period for which the Department has verifiable data.

(ii) At least 4,000 PET equivalents, for an applicant in a rural or micropolitan statistical area county, during the most recent 12-month period for which the Department has verifiable data.

(d) The applicant shall install the fixed PET unit at the same site as the existing approved host site.

(e) The applicant shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed PET scanner, including any temporary scanner used during the transition from mobile to fixed, becomes operational.

Section 5. Requirements for approval for applicants proposing to expand a PET scanner service

Sec. 5. (1) An applicant proposing to increase the number of fixed PET scanners (second, third, etc.) shall demonstrate the following:

(a) For an applicant in a metropolitan statistical area county, all of the applicant's approved fixed PET scanners have performed an average of at least 5,500 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(b) For an applicant in a rural or micropolitan statistical area county, all of the applicant's approved fixed pet scanners have performed an average of at least 5,000 pet equivalents per pet scanner during

the most recent 12-month period for which the department has verifiable data.

(c) In the case of a fixed PET scanner service, the additional PET scanner shall be located at the same geographic location as the existing fixed PET scanner service unless the applicant meets the applicable requirements for relocation in accordance with Section 9.

(2) An applicant proposing to increase the number of mobile PET scanners (second, third, etc.) shall demonstrate the following:

(a) For an applicant serving at least one existing host site in a metropolitan statistical area county, all of the applicant's approved mobile PET scanners on a mobile route have performed an average of at least 5,000 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(b) For an applicant serving only host sites in rural or micropolitan statistical area counties, all of the applicant's approved mobile PET scanners on a mobile route have performed an average of at least 4,500 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(3) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing to initiate a mobile PET scanner service.

(b) The applicant is currently a fixed PET scanner service.

(c) The applicant has demonstrated the following:

(i) For an applicant in a metropolitan statistical area county, all of the applicant's approved fixed PET scanners have performed an average of at least 5,500 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(ii) For an applicant in a rural or micropolitan statistical area county, all of the applicant's approved fixed PET scanners have performed an average of at least 5,000 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(d) At least two (2) separate CON applications have been submitted simultaneously as host sites for the proposed mobile PET service, subject to Section 4(3).

(e) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET service have been included in the CON application.

(f) The requirements of Section 3 have been met.

(g) The applicant agrees to comply with sections (13) and (14).

(h) The mobile unit must operate within the same planning area and comply with Section 4(2)(a).

Section 6. Requirements for approval for applicants proposing to replace a PET scanner

Sec. 6. (1) An applicant proposing to replace an existing fixed PET scanner(s) shall demonstrate that all of the applicant's approved and operating fixed PET scanners have performed an average of at least 4,500 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(2) An applicant proposing to replace an existing mobile PET scanner(s) shall demonstrate that all of the applicant's approved and operating mobile PET scanners on a mobile route have performed an average of at least 3,000 PET equivalents per PET scanner during the most recent 12-month period for which the Department has verifiable data.

(3) An exemption to subsections (1) and (2) may be made by the Department, if an applicant demonstrates to the satisfaction of the Department, the following:

(a) The existing PET scanner is technologically incapable of performing the applicable minimum number of PET equivalents. An applicant proposing a replacement under this subsection shall provide documentation, satisfactory to the Department, from a person or an organization with recognized

professional expertise regarding that type of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of equipment, indicating the number of PET equivalents the existing equipment is technologically capable of performing. The applicant also shall provide documentation, satisfactory to the Department, that the number of PET equivalents performed during the most recent 12-month period, for which the Department has verifiable data, was the number the equipment is technologically capable of performing.

(4) An applicant proposing to replace a PET scanner(s), whether fixed or mobile, shall demonstrate:

(a) the equipment to be replaced is fully depreciated according to generally accepted accounting principles or

(b) either of the following:

(i) the existing equipment clearly poses a threat to the safety of the public and the applicant's staff as determined by the Department or other qualified agency or individual (physicist, US Department of Energy, applicant's radiation safety committee, etc.) or

(ii) the proposed replacement PET scanner(s) offers technological improvements that enhance quality of care, increase efficiency, and reduce operating costs and patient charges.

(5) An applicant that meets all of the following requirements shall not be required to be in compliance with subsections (1), (2), (3) and (4):

(a) The existing PET scanner became operational before January 1, 2005 and is not PET/CT scanner hybrid.

(b) The proposed PET scanner is a PET/CT scanner hybrid.

(6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site as the applicant's existing fixed PET scanner to be replaced. If the proposed scanner will not be located at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed site, in accordance with Section 9.

Section 7. Requirements for approval for applicants proposing to acquire an existing PET scanner

Sec. 7. An applicant proposing to acquire an existing PET scanner, whether fixed or mobile, shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing PET scanner.

(b) The project will not change the number of PET scanners listed on the Department Inventory of PET Scanners.

(c) The project will not result in the replacement of the PET scanner to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

(d) The PET scanner to be acquired is listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department.

(e) The applicant agrees to operate the PET scanner in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

Section 8. Requirements for approval for applicants proposing to acquire an existing PET scanner service

Sec. 8. An applicant proposing to acquire an existing PET scanner service, whether fixed or mobile, shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing PET scanner service.

(b) The project will not change the number of Pet scanners listed on the Department Inventory of PET Scanners.

(c) The project will not result in the replacement of the PET scanners to be acquired unless the

applicant demonstrates that the requirements of Section 6 also have been met.

(d) All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department.

(e) The applicant agrees to operate the PET scanner service in accordance with all applicable project delivery requirements set forth in Section 14.

Section 9. Requirements for approval for applicants proposing to relocate an existing PET scanner service or its unit(s)

Sec. 9. (1) An applicant proposing to relocate an existing fixed PET service and all its existing unit(s) shall demonstrate that it meets all of the following:

(a) The service and all its existing units to be relocated are fixed PET scanners.

(b) The existing fixed PET service to be relocated has been in operation for at least 36 months as of the date of the application submitted to the Department.

(c) The proposed new site of the existing PET service to be relocated is in the relocation zone.

(d) The proposed project will not result in an increase in the number of PET scanner(s) operated by the applicant at the proposed site unless the applicant demonstrates that the requirements of Section 5, as applicable, have also been met.

(e) The proposed project will not result in the replacement of the PET scanner(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.

(f) The applicant agrees to operate the PET service and all its units in accordance with all applicable project delivery requirements set forth in Section 15 of these standards.

(2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate that it meets all of the following:

(a) The PET scanner to be relocated is a fixed PET scanner.

(b) The existing fixed PET service from which the PET scanner is to be relocated has been in operation for at least 36 months as of the date of the application submitted to the Department.

(c) The proposed new site for the PET scanner to be relocated is in the relocation zone.

(d) The proposed project will not result in the replacement of the PET scanner(s) to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.

(e) The applicant agrees to operate the PET scanner at the proposed site in accordance with all applicable project delivery requirements set forth in Section 15.

Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET scanner

Sec. 10. (1) An applicant proposing to operate a fixed PET scanner (whether new or replacement) to be used exclusively for research shall demonstrate each of the following:

(a) The PET scanner shall operate under a protocol approved by the applicant's Institutional Review Board.

(b) The applicant agrees to operate the PET scanner in accordance with the terms of approval in Section 14(1)(a), (b), (c)(vi), (d)(iii), (iv) and (v); 14(2); 14(3); and 14(4).

(c) The applicant has access to a cyclotron.

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 3, 4, 5, 6, 7, 8, 9 and 14(1)(c)(i), (ii), (iii), (iv), (v), (d)(i), and (d)(ii) of these standards.

Section 11. Requirements for approval for applicants proposing to establish a dedicated pediatric PET scanner

Sec. 11. (1) An applicant proposing to establish a dedicated pediatric PET scanner(s) shall demonstrate all of the following:

(a) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns, in the most recent year of operation.

(b) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(c) The applicant shall experience at least 50 new pediatric cancer cases on its cancer registry in the most recent year of operation.

(d) The applicant shall have an active medical staff at the time the application is submitted to the Department that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

- (i) pediatric radiology (at least two staff members)
- (ii) pediatric anesthesiology
- (iii) pediatric cardiology
- (iv) pediatric critical care
- (v) pediatric gastroenterology
- (vi) pediatric hematology/oncology
- (vii) pediatric neurology
- (viii) pediatric neurosurgery
- (ix) pediatric orthopedic surgery
- (x) pediatric pathology
- (xi) pediatric pulmonology
- (xii) pediatric surgery
- (xiii) neonatology

(e) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

- (i) pediatric bone marrow transplant program
- (ii) established pediatric sedation program
- (iii) pediatric open heart program

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 4 or Section 5 of these standards but must meet Section 6.

(6) The dedicated pediatric PET scanner shall be excluded from the adult count for the facility.

Section 12. Additional requirements for mobile PET service

Sec. 12. (1) An applicant proposing to begin operation of a mobile PET service shall demonstrate all of the following:

(a) A separate CON application has been submitted by the central service coordinator and each proposed host site.

(b) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET service have been included in the CON application.

(c) The requirements of sections 3, 4, 5, and 6, as applicable, have been met.

(2) An applicant proposing to become a host site on an existing mobile PET scanner service shall demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of mobile PET scanners listed on the "Department Inventory of PET Scanners" unless the requirements of Section 5 have been met.

(b) A proposed regular route schedule, the procedures for handling emergency situations, and copies of all proposed contracts related to the mobile PET scanner have been included in the CON

application.

Section 13. Requirements for approval for all applicants

Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 14. Project delivery requirements and terms of approval for all applicants

Sec. 14. (1) An applicant shall agree that, if approved, the services provided by the PET service shall be delivered in compliance with the following terms of CON approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable safety and operating standards.
- (c) Compliance with the following quality assurance standards:
 - (i) The approved PET scanner shall be operating at the applicable required volumes specified in these standards. In meeting this requirement, an applicant shall not include any patient visits conducted by dedicated research PET scanners.
 - (ii) An applicant shall establish and maintain (A) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of PET patient visits and (B) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.
 - (iii) A PET service, whether fixed or mobile, shall be staffed so that screening of requests for PET procedures and/or interpretation of PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The physician(s) must be on-site or available through telecommunication capabilities to participate in the screening of patients for PET procedures and to provide other consultation services.
 - (iv) An applicant shall establish a PET service team. A PET service team shall be responsible for (A) developing criteria for procedure performance, (B) developing protocols for procedure performance, (C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a mobile pet service(s)/scanner(s).
 - (v) At a minimum, the PET service team shall include the following personnel, employed directly by the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified or eligible for certification by the American Board of Radiology or an equivalent organization. Other personnel that may be appropriate members of the PET service team, depending on the type of operation and PET procedures performed, include but are not limited to nurses, computer technicians, radio-chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the team leader is not a physician, the PET service team also shall include a physician with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined.
 - (vi) The applicant shall have, within the PET service, equipment and supplies to handle clinical emergencies that might occur within the PET service, with PET staff trained in CPR and other appropriate emergency interventions, and a physician on-site or immediately available to the PET service at all times when patients are undergoing PET procedures.
 - (vii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two

years of operation and continue to participate annually thereafter.

(viii) Fixed and mobile PET scanner units shall be operating at a minimum average annual level of utilization during the second twelve months of operation, and annually thereafter, of 1,500 PET equivalents per unit.

(d) Compliance with the following requirements:

(i) The applicant shall accept referrals for PET scanner services from all appropriately licensed practitioners.

(ii) The applicant, to assure that the PET scanner services will be utilized by all segments of the Michigan population, shall (A) not deny PET scanner services to any individual based on ability to pay or source of payment, (B) provide PET scanning services to any individual based on the clinical indications of need for the service, and (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but are not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department or its designee. The applicant shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or PET service as required by the Department, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. If the applicant intends to include research PET equivalents conducted by a PET scanner other than a dedicated research PET scanner in its utilization statistics, the applicant shall submit to the Department a copy of the research protocol with evidence of approval by the Institutional Review Board. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall separately report to the Department any PET equivalents conducted by a dedicated research PET scanner.

(iv) PET equipment to be replaced shall be removed from service on or before beginning operation of the replacement equipment, including the use of temporary scanners as part of the replacement project.

(v) The applicant shall provide the Department with a notice stating the first date on which the PET scanner became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the dedicated research PET scanner approved pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The dedicated research PET scanner approved pursuant to Section 10 shall not be used for any purposes other than as approved by the Institutional Review Board unless the applicant has obtained CON approval for the PET scanner pursuant to Part 222 and these standards, other than Section 10.

(3) The operation of and referral of patients to the PET service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 15. Project delivery requirements and additional terms of approval for applicants involving mobile PET services

Sec. 15. (1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) The central service coordinator for a mobile PET service, with an approved CON, shall notify the administrative unit of the Department of Community Health responsible for administering the CON program 30 days prior to dropping an existing host site.

(b) Each host site must have at least one physician who is board certified or board eligible in nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i) establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans performed by the mobile PET service/scanner.

(c) Each mobile PET scanner service shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least once a week or in accordance with the manufacturer's requirements, during hours not normally used for patient procedures.

(e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit, of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor). Each host site also must provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile PET scanner service shall operate under a contractual agreement that includes the provision of PET services at each host site on a regularly scheduled basis.

(g) The volume of utilization at each host site shall be reported to the Department by the central service coordinator under the terms of Section 14(1)(d)(iii).

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or the governing body of the applicant or its authorized agent.

Section 16. Determination of PET equivalents

Sec. 16. For purposes of these standards, PET equivalents shall be calculated as follows:

(a) Each actual patient visit performed during the time period specified in the applicable section(s) of these standards shall be assigned a number of PET equivalents based on the sum of the applicable values set forth in subsections (i) through (vii).

(i) A single patient visit 1.0

(ii) Number of chemically different tracers used during a single patient visit.

1 tracers = 0

≥2 tracers = 0.8

(iii) Number of tracer injections performed during a single patient visit.

1 tracer injection = 0

2 tracer injections = 0.3

≥3 tracer injections = 0.6

- (iv) Dynamic scan(s) performed during a single patient visit. 0.5
- (v) Number of bed positions used during a single patient visit.
 1 bed position = 0
 ≥ 2 bed positions = 0.2 for each additional position
- (vi) Arterial sampling performed during a single patient visit. 0.5
- (vii) Transmission scan .1 per bed position

Total PET Equivalents for a Single Patient Visit

- (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a) shall be multiplied as follows:
 patient ≤ 5 years of age multiply by 4.0
 patient $>5 \leq 10$ years of age multiply by 3.0
 patient $>10 \leq 17$ years of age multiply by 2.0
- (c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to subdivision (a) shall be multiplied by 1.5.
- (d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c) shall be summed to determine the total PET equivalents for the time period specified in the applicable section(s) of these standards.

Section 17. Methodology for computing the projected number of PET data units

Sec. 17. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of PET data units.

- (1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the requirements of Section 18.
- (b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470 OR C490 excluding C440-C444 (skin of head and neck), and additional codes approved by National Coverage Determination]. Use the name "combined" for this grouping.
- (c) Multiply the number resulting from the calculation in "combined" cancer cases identified in subsection (1)(b) by 0.8, which is the estimated probability that a "combined" cancer case will require a PET scan.
- (d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the estimated number of PET scans needed for each patient requiring a PET scan.
- (2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the requirements of Section 18.
- (b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the estimated probability that a breast cancer case will require a PET scan.
- (c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.
- (3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic cardiac catheterization will require a PET scan.
- (b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.
- (4)(a) Multiply the number of intractable epilepsy cases (ICD-9-CM Codes 345.01, 345.11, 345.41,

345.51, 345.61, 345.71, 345.81, OR 345.91) identified in accord with the requirements of Section 21 by 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require a PET scan.

(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the total number of projected PET data units.

(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is proposing to serve only Planning Area 6 to determine the total number of projected PET data units.

(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is proposing to serve only Planning Area 5 to determine the total number of projected PET data units.

Section 18. Commitment of diagnosis specific new cancer cases

Sec. 18. (1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the following:

(a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.

(b) Each entity contributing diagnosis specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis specific cancer cases being committed to the application and that states no current or future diagnosis specific new cancer case data will be used in support of any other application for a PET unit for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis specific new cancer case data is in the same planning area as the proposed PET service.

(d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis specific new cancer case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(e) No entity contributing diagnosis specific new cancer case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service and is listed on the "Department Inventory of Pet Scanners."

(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.

(3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been issued unless the application is denied, withdrawn, or expired.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 19. Documentation of diagnosis specific new cancer case data

Sec. 19. (1) An applicant required to document volumes of diagnosis specific new cancer cases shall submit, as part of its application at the time it is submitted to the Department, documentation from the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer cases provided in support of the application for the most recent calendar year for which verifiable data are available from the State Registrar. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(2) Diagnosis specific new cancer case data supporting an application under these standards shall be submitted to the Division for Vital Records and Health Statistics using a format and media specified in instructions from the Department of Community Health.

Section 20. Commitment and documentation of diagnostic cardiac catheterization data

Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all of the following:

(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)] provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that states no current or future diagnostic cardiac catheterization data will be used in support of any other application for a PET unit for the duration of the PET service for which data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization data is in the same planning area as the proposed PET unit/service.

(c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis specific new cancer case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(d) No entity contributing diagnostic cardiac catheterization data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service and is listed on the "Department Inventory of Pet Scanners."

(e) The diagnostic cardiac catheterization case data is from the most recently completed report(s) of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity has CON Approval to provide diagnostic cardiac catheterization services.

(2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile, listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization case data.

(3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied unless the application is denied, withdrawn, or expired.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the

signature.

Section 21. Commitment and documentation of intractable epilepsy data

Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the following:

(a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of intractable epilepsy cases committed to the application and that states no current or future intractable epilepsy case data will be used in support of any other application for a PET unit for the duration of the PET service for which the data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(b) For fixed PET scanner services, the geographic location of each entity contributing intractable epilepsy case data is in the same planning area as the proposed PET unit/service.

(c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis specific new cancer case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(d) No entity contributing intractable epilepsy case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service and is listed on the "Department Inventory of Pet Scanners."

(e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB) available to the Department.

(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.

(3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application unless the application is denied, withdrawn, or expired.

(b) The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 22. Health Service Areas

Sec. 22. Counties assigned to each health service area are as follows:

HEALTH SERVICE AREA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

Section 23. Planning Areas

Sec. 23. Health service areas assigned to each planning area are as follows:

PLANNING AREA 1

COUNTIES

HSA 1

Livingston
Macomb
Wayne

Monroe
Oakland

St. Clair
Washtenaw

PLANNING AREA 2

HSA 2

Clinton
Eaton
Barry
Berrien
Branch

Hillsdale
Ingham
Calhoun
Cass
Kalamazoo

Jackson
Lenawee
St. Joseph
Van Buren

PLANNING AREA 3

HSA 4

Allegan
Ionia
Kent
Lake

Mason
Mecosta
Montcalm
Muskegon

Newaygo
Oceana
Osceola
Ottawa

PLANNING AREA 4

HSA 5

HSA 6

Genesee
Arenac
Bay
Clare
Gladwin
Gratiot

Lapeer
Huron
Iosco
Isabella
Midland
Ogemaw

Shiawassee
Roscommon
Saginaw
Sanilac
Tuscola

PLANNING AREA 5

HSA 7

Alcona
Alpena
Antrim
Benzie
Charlevoix
Cheboygan

Crawford
Emmet
Gd Traverse
Kalkaska
Leelanau
Manistee

Missaukee
Montmorency
Oscoda
Otsego
Presque Isle
Wexford

PLANNING AREA 6

HSA 8

Alger
Baraga
Chippewa
Delta
Dickinson

Gogebic
Houghton
Iron
Keweenaw
Luce

Mackinac
Marquette
Menominee
Ontonagon
Schoolcraft

Section 24. Department Inventory of PET Scanners

Sec. 24. The Department shall maintain and provide upon request a listing of the Department Inventory of Pet Scanners as of the effective date of these standards.

Section 25. Comparative reviews; effect on prior planning policies

Sec. 25. (1) Proposed projects reviewed under these standards shall not be subject to comparative review except for applicants under Section 4(4) that may be subject to comparative review.

(2)(a) These CON review standards supersede and replace the CON Standards for Positron Emission Tomography approved by the CON Commission on March 9, 2004 and effective June 4, 2004.

**CON REVIEW STANDARDS
FOR PET SCANNER SERVICES**

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget